IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE ENTRESTO (SACUBITRIL/VALSARTAN) PATENT LITIGATION	MDL No. 20-2930-RGA
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. TORRENT PHARMA INC., TORRENT PHARMACEUTICALS LTD., Defendant.	C.A. No. 19-1979-RGA
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. ALEMBIC PHARMACEUTICALS LIMITED, ALEMBIC GLOBAL HOLDING SA, ALEMBIC PHARMACEUTICALS, INC., Defendants.	C.A. No. 19-2021-RGA

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. HETERO USA INC., HETERO LABS LIMITED, HETERO LABS LIMITED UNIT III, MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, MSN LIFE SCIENCES PRIVATE LIMITED, Defendants.	)	C.A. No. 19-2053-RGA

FINAL JUDGMENT

WHEREAS Defendants Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. (collectively, "Alembic"); Hetero USA Inc., Hetero Labs Limited and Hetero Labs Limited Unit III (collectively, "Hetero"); MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited (collectively, "MSN"); and Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. (collectively, "Torrent") (Hetero, MSN, and Torrent are collectively, "Defendants") each have submitted Abbreviated New Drug Applications ("ANDAs") to the FDA seeking approval to market generic versions of Plaintiff Novartis Pharmaceuticals Corporation's ("Plaintiff's") Entresto® (sacubitril and valsartan) 24/26 mg, 49/51 mg, and 97/103 mg products;

WHEREAS the Court construed certain terms in the claims of U.S. Patent No. 8,101,659 ("'659 patent") in a Memorandum Opinion and Order dated July 8, 2021 (MDL No. 20-2930-RGA, D.I. 294, 295);

WHEREAS Hetero, MSN, and Torrent each stipulated, subject to the respective terms of the Stipulation applicable to that Defendant, and to the extent that claims 1-4 of the '659 patent are valid, that the filing of its respective ANDA infringed each of claims 1-4 of the '659 patent"), and that the products described in its respective ANDA, if approved by FDA, would infringe each of claims 1-4 of the '659 patent (MDL No. 20-2930-RGA, D.I. 526, 709, 710) ("Stipulations");

WHEREAS C.A. No. 19-2021-RGA and MDL No. 20-2930-RGA were stayed as to Alembic; Alembic agreed to be bound by any final judgment, from which no appeal can be taken other than a writ of certiorari to the Supreme Court of the United States, on the validity and enforceability of the asserted claims of the '659 patent; Alembic agreed not to contest the validity and enforceability of the asserted claims of the '659 patent, and thus Alembic did not participate in trial on the merits in C.A. Nos. 19-1979-RGA, 19-2021-RGA, and 19-2053-RGA, consolidated under MDL No. 20-2930-RGA (*see* MDL No. 20-2930-RGA, D.I. 519);

WHEREAS this matter came before the Court for trial on the merits in C.A. Nos. 19-1979-RGA, 19-2021-RGA, and 19-2053-RGA, consolidated under MDL No. 20-2930-RGA, to resolve the questions of whether claims 1-4 of the '659 patent are invalid: (i) as obvious under 35 U.S.C. § 103, (ii) for lack of enablement under 35 U.S.C. § 112, (iii) for lack of written description under 35 U.S.C. § 112, and (iv) as indefinite under 35 U.S.C. § 112;

WHEREAS the Court has heard the testimony of Plaintiff's and Defendants' witnesses and has considered the evidence submitted by the parties, and the Court has reviewed the post-trial submissions of the parties; and

WHEREAS notwithstanding Alembic's stayed status in the above-captioned actions, Plaintiff, Hetero, MSN, and Torrent agree under Fed. R. Civ. P. 54(b) that the Court may direct

entry of a final judgment as to Plaintiff, Hetero, MSN, and Torrent because there is no just reason for delay;

IT IS ORDERED that pursuant to Fed. R. Civ. P. 54(b), there is no just reason to delay entry of a final judgment as to Plaintiff's claims and Defendants' counterclaims related to the '659 patent; and it is further

ORDERED that the Stipulations for the Defendants (MDL No. 20-2930-RGA, D.I. 526, 709, 710), as pertaining to the '659 patent, are incorporated into this Final Judgment, and that, on the basis of those Stipulations and as limited in those Stipulations, and to the extent that claims 1-4 of the '659 patent are valid, Final Judgment is hereby entered pursuant to Fed. R. Civ. P. 54(b) in favor of Plaintiff and against Defendants that the filing of their respective ANDAs infringed each of claims 1-4 of the '659 patent, and that the products described in Defendants' respective ANDAs, if approved by FDA, would infringe each of claims 1-4 of the '659 patent; and it is further

ORDERED AND ADJUDGED, for the reasons set forth in the Court's Trial Opinion dated July 7, 2023 (MDL No. 20-2930-RGA, D.I. 1099), that Final Judgment is hereby entered pursuant to Fed. R. Civ. P. 54(b) in favor of Plaintiff and against Defendants, that claims 1-4 of

the ’659 patent were not proven to be invalid: (i) as obvious under 35 U.S.C. § 103; (ii) for lack of enablement under 35 U.S.C. § 112; and (iii) as indefinite under 35 U.S.C. § 112; and it is further

ORDERED AND ADJUDGED, for the reasons set forth in the Court’s July 7, 2023 Trial Opinion, that Final Judgment is hereby entered pursuant to Fed. R. Civ. P. 54(b) in favor of Defendants and against Plaintiff, that claims 1-4 of the ’659 patent are invalid for lack of written description under 35 U.S.C. § 112; and it is further

ORDERED that all interlocutory decisions, orders, rulings, findings, and/or conclusions related to the ’659 patent merge into this judgment; and it is further

ORDERED that Plaintiff and Defendants agree that any and all appeals from this judgment in this consolidated action should be consolidated into a single appeal; and it is further

ORDERED that each party shall bear its own costs and fees.

Dated this 21 day of July, 2023

/s/ Richard G. Andrews

United States District Court Judge